REPORT OF A

GOOD LABORATORY PRACTICE (GLP) INSPECTION:

COMPLIANCE REVIEW AND STUDY AUDITS

CONDUCTED PURSUANT TO THE

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

FACILITY: **MicroBioTest, Inc.**
A Division of Microbac Laboratories
1105B Carpenter Drive
Sterling, Virginia 20164

INSPECTION NO: 201139553401

RESPONSIBLE OFFICIAL: Mr. Nathan Jones
Director, Quality Assurance
PH: 703. 925. 0100
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DATES OF INSPECTION: April 26 -29, 2011
LAST INSPECTION DATE: December 4, 2006

Inspector: Elmer Griffin
U.S. EPA, Washington, D.C.
PH: 202 .564 .4132

Audit Team: Francisca Liem
U.S. EPA, Wash., D.C.
Director GLP Program

&

Elmer Griffin
Inspector

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Appendix C. **Bleach-Rite Disinfecting Spray with Bleach**, [a.i.: Sodium hypochlorite];
Confirmatory Virucidal Efficacy Test - Feline Calicivirus (Surrogate for Human Norovirus); Laboratory Project Numbers: 611-111; EPA (MRID) Number: 48161711; EPA Product Reg No. 70590-2;
Registrant/Sponsor: Current Technologies, Inc. (ID #: 070590), Crawfordsville, IN

Appendix D. **Aquatabs**, [a.i.: Sodium dichloroisocyanurate];
EPA Water Purifier Challenge Test Using Giardia muris Cysts: Aquatabs; Laboratory Project Number: 642-115; EPA (MRID) Number: 48223205; Product Reg No. 71847-4; Registrant/Sponsor: Medentech, Ltd. (071847) Wexford, Ireland: Agent - Clearon Corporation, South Charleston, WV

Appendix E. **Cavicide 1**, [a.i.: Ethanol, Isopropanol, Didecyl dimethyl ammonium chloride]; Amended Final Report: AOAC Germicidal Spray Test Healthcare; Laboratory Project Number: 198-524; EPA (MRID) Number: 48343911; Product Reg No. 46781-12; Registrant/Sponsor: Metrex Research, LLC (046781): Agent: Cybron Dental Specialties, Orange, CA

Appendix F **Cavicide 1**, [a.i.: Ethanol, Isopropanol, Didecyl dimethyl ammonium chloride]; AOAC Tuberculocidal Activity of a Germicidal Spray; Laboratory Project Number: 198-529; EPA (MRID) Number: 48343912; EPA Product Reg No. 46781-12;
Registrant/Sponsor: Metrex Research, LLC (046781);
Agent: Cybron Dental Specialties, Orange, CA

I. SUMMARY OF FINDINGS

A GLP compliance inspection was conducted at MicroBioTest, Inc., Sterling, Virginia during April 26 thru 29, 2011. The GLP compliance inspection consisted of a compliance review and five study audits.

The findings for the compliance review (ongoing study and facility inspection) revealed:

1. Study records located in the archives were not documented and indexed to permit expedient retrieval, **Citation: 40 CFR §160.190 (e).**
2. The master schedule was not completely filled out. Some entries were blank or not completed. **Citation: 40 CFR Part 160.35 (b) (1).**
3. No protocol amendments were written for unused test substances not returned to sponsor after 3 months of study completion, **Citation: 40 CFR §160.120 (b).**
4. The QA needs to submit periodically to management a written status report on each study, **Citation: 40 CFR §160.35 (b) (4).**
5. The chain of custody records indicated the QAU was involved in the study by logging the test substance in the facility from the courier services and out to the study director. **Citation: 40 CFR §160.35 (a).**
6. No chain of custody records, shipping records to document and verify receipt of the test substance. **Citation: 40 CFR §160.107 (d).**
7. The equipment log (i.e. pH meter) should be more descriptive detailed to include the study's laboratory project number.
8. The retain test substance archives (chemical archives) were stored together with the current test substances in the chemical storage room. There were no separation between the retained test substances and the ongoing test substances, **Citation: 40 CFR §160.47 (b).**
9. Limited access to the archives room was not in place at all times. The archivist would give the key to the study director who would log out the documents to remove it from the archives. **Citation: 40 CFR 106.190 (d).**

The findings pertaining to the study audits were:

1. The final report lacked the names of scientists involved in the study, **Citation: 40 CFR Part 160.185 (a) (10).**
2. The final report lacked the location of the raw material, data and final report, **Citation: 40 CFR §160.185 (a) (13).**
3. The final report did not describe the objective of the study and the criteria for "passing". **Citation: 40 CFR §160.185 (a) (11), 40 CFR §160.185 (a) (2).**
4. The chain of custody records indicated the QAU was involved in the study by logging the test substance in the facility from the courier services and out to the study director. **Citation: 40 CFR §160.35 (a).**

5. Lack of shipping/receiving invoice for test substance and could not confirm the test substance lots/batches from the original source.
   Citation: 40 CFR §160.107 (d).
6. Lack of receipt/invoice for test system (Mycobacterium bovis); could not confirm the microorganisms' lots number, original source and shipment date.
   Citation: 40 CFR §160.195 (b).
7. No protocol amendment to reflect the test substances left over was not returned to the sponsor three months after study completion.
   Citation: **40 CFR Part 160.120 (b)**
8. The protocol indicates the records to be maintained but should be expanded to a list of raw data. **Citation: 40 CFR 160.120 (a) (13)**.
9. The QA statement stated that an "in-process" activity was carried out. The "in-process" activity should be identified as what phase was inspected.
   Citation: 40 CFR Part 160.35 (b) (3).
10. The quality assurance quarterly inspection report (which was a modify status report) did not indicate the name of the study and type of study, the type of findings and the phase inspected. **Citation: 40 CFR §160.35 (b)(4)**.
11. Need to improve the SOP for quality assurance to report phase inspection to study director and management. **Citation: 40 CFR §160.81(b)**.
12. The chemicals archive for storage of test substances, reference standards and reagents on shelves were disorderly. There was no separation of chemicals used for the current
    studies and completed studies. **Citation: 40 CFR §160.190 (b).**
13. No chemical characterization data was provided to the inspection team and the test facility. Letters to notify the sponsor of a GLP inspection was mailed and faxed before the inspection date requesting that chemical characterization data be sent to MicroBiotest. **Citation: 40 CFR §160.105 (a), 40 CFR 160.105 (b).**
14. The pH meter was not calibrated for the test samples for this study. The pH meter is calibrated once the day of testing and for another study. The pH log did not indicate any calibration for the study sample set. **Citation: 40 CFR Part 160.63 (c)**.

II. INTRODUCTION

A FIFRA Good Laboratory Practice Standards compliance review and study audits were conducted at MicroBioTest, Inc., Sterling, Virginia, on April 26 - 29, 2011 at the request of the Office of Compliance (OC), Office of Enforcement and Compliance Assurance (OECA). Mr. Nathan Jones, was notified of the scheduled inspection by letter (Exhibit 1) from Ms. Francisca E. Liem, Director, Good Laboratory Practice Program (GLPP). The letter identified the inspector, the studies to be audited, and the data and records to be made available. The compliance inspection was led by Mr. Elmer Griffin and the study audits were conducted by Mr. Elmer Griffin and Ms. Liem (GLPP).

III. OPENING CONFERENCE

An opening conference began 9:15 a.m. on Tuesday, April 26, 2011 in the facility's conference room. The company officials present during the opening conference were:

1. Mr. Nathan Jones, Director, Quality Assurance,
2. S. Steve Zhou, Ph.D., Section Director, Virology and Microbiology and
3. Ms. Angela Holinsworth, Director, Laboratory Operations.

The Agency was represented by Mr. Elmer Griffin, Inspector/ Auditor and Ms. Francisca E. Liem Director, GLP Program, OCEA/OC/MAMPD, EPA, Washington, D.C.

Official credentials and an FIFRA Notice of Inspection (Exhibit 2) were presented to Mr. Jones who was advised that the inspection was routine and that no suspected discrepancies were involved. The inspector discussed the background, purpose, and schedule for the inspection, and the records and procedures to be reviewed. A facility tour of MicroBiotest was conducted at the Sterling, Virginia facility.

IV. HISTORY OF FACILITY

MicroBiotest is an antimicrobial efficacy lab performing microbiological and virological testing in accordance with the U.S. E.P.A. and U.S. F.D.A. guidelines. Areas of testings included air and surface sanitizers, disinfectants/sterilants, medical devices, biocides, water purifiers and other types of tests. Ms. Donna B. Suchmann was the founder and CEO of MicroBiotest for over twenty years before its acquisition with Microbac Laboratories, Inc. on December 1, 2009. Microbac Laboratories provides testing in numerous areas such as environmental, food microbiology, nutritional labeling, pharmaceuticals, agrochemical testing, etc. Most of these areas have certified testing services. The addition of MicroBiotest provided Microbac to expand in the area of virology. Microbac's headquarters is located in Pittsburgh, Pennsylvania. It's laboratories are located in at least 13 states of U.S.A. and has at least two or more laboratories in 7 of those states.

V. EXIT CONFERENCE

The exit conference was held on April 29, 2011 at 12:00 pm to review the findings and recommendations of the GLP Standards compliance review and study audits. The inspector emphasized improvements that should be made with regard to functions of the quality assurance unit, the contents of the final report and protocol, and the distribution, receipt and archiving of test, control and reference substances. Exhibit 6 - MicroBiotest response to Inspection.

The inspector provided MicroBiotest, Inc. with a FIFRA Receipt for Samples: Form 3540-3 (Exhibit 3), and the Inspection Observation: Form 3540-38 (Exhibit 4). The inspection was concluded around 1:00 p.m.

VI. LIST OF EXHIBITS

Exhibit 1 MicroBiotest, Inc.'s Notification Letter of GLP Inspection.

Exhibit 2 FIFRA Notice of Inspection

Exhibit 3 FIFRA Receipt of Samples

Exhibit 4 Inspection Observations

Exhibit 5 MicroBiotest's Capability Statement

Exhibit 6 Microbiotest's response to inspection.

SIGNATURE

E Griffin

Elmer Griffin, Env. Scientist
OECA/OC/MAMPD

Feb 12, 2012

Date